







The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients

Submission date 02/10/2011	Recruitment status No longer recruiting	 Prospectively registered
		 Protocol not yet added
		 SAP not yet added
Registration date 28/10/2011	Overall study status Completed	 Results not yet added and study completed for more than 2 years
Last Edited 06/12/2012	Condition category Nervous System Diseases	 Raw data not yet added
		 Study completed

Plain English Summary

Background and study aims:

Postherpetic neuralgia (PHN) is a nerve pain that occurs at the site of a previous attack of a condition called shingles. Neuralgia is a term that describes nerve pain. Postherpetic neuralgia is nerve pain which continues 3-6 months after the shingles rash has healed. PHN can have a severe impact on a patients quality of life. The health care costs related to persistent PHN puts a heavy economic burden and stress on families and societies. Unfortunately, PHN is often does not respond very well to the existing treatments.

The aim of this study is observe the effect of pregabalin in PHN patents. Treatment of PHN with pregabalin is safe and effective in relieving pain and sleep interference. However, to date no known studies investigating the effect of pregabalin on the central nerve system measured using functional Magnetic Resonance Imaging.

Who can participate?

Patients diagnosed with postherpetic neuralgia, aged over 60 years and weighing over 40kg.

What does the study involve?

Participants were randomly allocated to one of two 2 groups:

Pregabalin group), which received pregabalin twice a day for 14 days.

Placebo group, which received a placebo (dummy drug) twice a day for 14 days.

Oxycodone was used as rescue medication for pain if required.

What are the possible benefits and risks of participating?

All participants received treatments which may improve the symptoms of PHN.

There were no known risks associated with participating in this trial.

Where is the study run from?
Pain Management Center, Xinhua Hospital

When is the study starting and how long is it expected to run for?
Participants were enrolled the study between December 2011 and November 2012 and follow-up examinations will continued until December 2012.

Who is funding the study?
Shanghai Education Committee, China ref: 11YZ56

Who is the main contact?
Prof M A Ke,
macoo72@163.com

Contact information

Type(s)
Scientific

Contact name
Prof MA Ke

Contact details
Department of Anesthesiology
Xinhua Hospital
Shanghai Jiaotong University School of Medicine
1665 Kongjiang Road
Shanghai
China
200092
macoo72@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
N/A

Study information

Scientific Title
The clinical study of effect of pregabalin to functional Magnetic Resonance Imaging (fMRI) and Iowa Gambling task (IGT) in postherpetic neuralgia patients: a prospective, double blind, randomised controlled trial

Study hypothesis

1. That fMRI signal and IGT were different among postherpetic neuralgia (PHN) patients and control patients.
2. The drug (pregabalin) can affect signal of fMRI, the outcome of IGT, quality of life and reduce the oral pain-related drugs dosage of PHN patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

Xinhua Hospital affiliated to Shanghai Jiaotong University School of Medicine, 17 of March 2011, ref: 2011-003

Study design

Prospective double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Condition

Postherpetic neuralgia

Interventions

PHN patients were randomized to receive pregabalin 150mg twice a day (Bid) or placebo for 2 weeks.

Rescue medication: Oxycodone 5-30mg/day or more orally was used as rescue medication for pain controlled at VAS more than 3 and the frequency of acute pain flares more than 3 times per day.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Pregabalin

Primary outcome measure

1. fMRI signal change, IGT results at baseline, days 14 after treatment
2. Visual Analogue Scale (VAS), measured at baseline, days 1, 2, 3, 7, 14 after treatment
3. Flare pain per day during days 3, 7, 14 after treatment

Secondary outcome measures

1. SF-36 at baseline, days 14 after treatment
2. Dosage of rescue drug (Oxycodone) consumed per day at days 3, 7, and 14 after treatment
3. Presence, frequency and duration of adverse effects at 7, 14 days

Overall study start date

01/12/2011

Overall study end date

30/12/2012

Eligibility

Participant inclusion criteria

1. Age greater than 60 years and over 40kg of body weight
2. Pain history is longer than 3 months
3. Pain on Visual Analogue Scale (VAS) >3 (0-10 VAS scale), the frequency of acute pain flares occurred more than 3 times per day
4. Refractory to formal treatment such as antiepileptic medicine, antidepressants, opioids and physical treatments and epidural block
5. No history of severe liver and renal diseases

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40 patients

Participant exclusion criteria

1. Withdraws from the study
2. Poor effect, intolerant to the study
3. Uncooperative and unable to finish the self evaluation (VAS, quality of life [QOL] and SF-36)
4. Coagulation disturbances
5. Allergies to drug
6. Malignancy

Recruitment start date

01/12/2011

Recruitment end date

30/12/2012

Locations

Countries of recruitment

China

Study participating centre

Department of Anesthesiology

Shanghai

China

200092

Sponsor information

Organisation

Xinhua Hospital (China)

Sponsor details

Department of Anesthesiology

Shanghai Jiaotong University School of Medicine

1665 Kongjiang Road

Shanghai

China

200092

Marke72@163.com

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04dzvks42>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration